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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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In re Application of	:	
Jae Keol Rhee et al.	:	
Serial No.: 10/596,412	:	DECISION ON PETITION
Filed: 13 June 2006	:	
Attorney Docket No.: TRIUS.002NP	:	

This letter is in response to the Petition under 37 C.F.R. 1.181 filed on 14 September 2009 requesting review and withdrawal of restriction requirement set forth in the Final Office action dated 13 August 2009.

BACKGROUND

This application was filed as a national stage application in compliance with under 35 U.S.C. 371 and as such is subject to PCT unity of invention practice.

On 6 March 2008, the examiner mailed a restriction requirement dividing the claims into Groups I-XI, directed to various compounds, based upon the variable selected for "X" and Groups XII-XIV, directed to various processes. Group XV was directed to another compound. The restriction requirement acknowledged that the application was eligible for concurrent examination of one product, one process of making the product and one process of using the product per PCT Unity Of Invention criteria. The action then assured applicants that

> Claims 1-13,16, 23-30 and 47-50 will be examined to the extent readable on the elected compounds.

On 19 March 2008, applicant elected Group VIII for examination.

On 23 June 2008, claims 1-17 and 21-50 were withdrawn from consideration as being directed to non-elected inventions. The examiner stated that claim 21 had been inadvertently placed in Group VIII, because it was not drawn to the claimed halogenation reaction.

> Claims 18-20 were rejected under 35 USC 102(e) as being anticipated by Chin.
>
> Claims 18-20 were rejected under 35 USC 103(a) as being unpatentable over Chen, Fukuda and Barachyn.

On 16 December 2008, the Office action mailed 23 June 2008 was vacated and apparently re-mailed as a non-final Office action with little, if any, substantive change.

On 29 January 2009, the Office action mailed 16 December 2008 was vacated and a new non-final Office action was mailed which addressed claims 17-22 on the merits.

On 11 February 2009, the Office action mailed 29 January 2009 was vacated and a new non-final Office action was mailed which addressed Claims 17-22 and 36-46. The restriction requirement amongst Groups XII-XIV was withdrawn.

> Claims 17-22 and 36-46 were rejected under 35 USC 102(e) as being anticipated by Chin.
>
> Claims 17-22 and 36-46 were rejected under 35 USC 103(a) as being unpatentable over Chen, Fukuda and Barachyn.

On 11 May 2009, applicants filed a response to the Office action which cancelled claims 1-50 and added new claims 51-99.

On 13 August 2009, in a final Office action, the examiner withdrew claims 53-99 as being directed to non-elected subject matter which was independent and distinct from originally elected process. Claims 51-52 were rejected under 35 USC 103(a) as being unpatentable over Chen, Fukuda and Barachyn. Claim 52 was rejected under 35 USC 112, 2nd paragraph as being indefinite.

Applicants filed an after final reply on 27 August 2009 requesting consideration of the withdrawn claims.

On 4 September 2009, the examiner mailed an advisory action, indicating that the amendment filed after final would not be entered and that because the election had been made without traverse, and because applicants had elected the process invention, rejoinder was not applicable.

On 14 September 2009, applicants filed a Notice of Appeal, a pre-appeal brief request and this petition under consideration.

DISCUSSION

The petition and file history have been carefully considered.

At the onset, the following irregularities have been noted, which are useful in addressing applicant's first request that the finality of the Office action mailed 13 August 2008 be withdraw:

First, this application is the national stage filing of PCT/KR04/003327 and, as such, is eligible for PCT unity of invention practice. In the final Office action dated 13 August 2009, the examiner relied upon the criteria of *independence and distinction* to conclude that claims 54-99 were directed to a different invention. This is not proper. The examiner should have followed guidelines in MPEP Chapter 1800, PCT Rule 13.2 and International Search and Examination Guidelines Chapter 10 to determine whether the invention shared a special technical feature or were of general similar nature such that unity was present.

For this reason alone, the Office action mailed 13 August 2008 is incorrect and will be withdrawn. Because the final Office action has been withdrawn, the amendment filed 27 August 2009 will be entered.

Second, while the national stage filing is entitled to PCT Unity of Invention practice with regard to any restriction or election of species requirement, examination of a national stage filing must comport with US practice per 35 USC 372(a),

> All questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office.

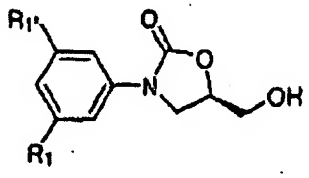
Third, the examiner appears to placing undue weight upon the fact that applicants made their original election without traverse. This is inappropriate for two reasons.

> (a) Applicant's original election was made following the assurance that the elected product, and its first process of making and process of using inventions would be examined together. The examiner did not honor that assurance in the subsequent Office actions.
>
> (b) Acquiescing to an original restriction requirement does not in any way prevent applicants from traversing or petitioning any second or subsequence restriction requirement. Here, the subsequent restriction requirement was timely traversed in the after final amendment. Because the petition under 37 CFR 1.181was filed within two months of the advisory action, it is considered timely and proper.

Fourth, in the first Office action on the merits, the examiner has, on one hand, withdrawn an independent claim 17 directed to a method of preparing an oxazolidinone derivative of Formula

(I) while on the other hand, examined claims 18, 19 and 20m each of which directly depends upon and further limits the method of withdrawn claim 17. This is improper.

18. (new): The method of claim 17, wherein the compound of Formula (III) is obtained by halogenating a compound of Formula (II):



(II),

wherein R_1 and R_1' each have the same meanings as defined in claim 17.

19 (new): The method of claim 17, wherein R_1 is fluorine, R_1' is either hydrogen or fluorine, and Y represents a halogen.

20. (new): The method of claim 17, wherein Y is iodine.

Fifth, in the first Office action on the merits, the examiner withdrew claims 1-13, 16, 23-30 and 47-50 which applicants had been assured would be examined to the extent readable on the elected compounds. By withdrawing these claims, the examiner is altering the restriction requirement without giving applicants reasons for this action or providing applicants with the opportunity to change their election. This is not correct.

Sixth, during preparation of the Final Office action, the examiner appears to have confused claim format (independent versus dependent claims) with independent and dependent (related) inventions. It is not the format of the claims, but rather the substance of the subject matter which determines whether restriction or lack of unity holding is appropriate. It is noted that examined Claims 52 depends upon examined claim 51 while withdrawn claims 54-99 depend upon withdrawn claim 53.

Seventh, the original lack of unity determination placed the process claims in Groups XII, XIII and XIV. In the Supplemental non-final Office action mailed 11 February 2009, the restriction requirement between Groups XII, XIII and XIV was withdrawn, such that the process claims which were pending on 11 February 2009 were examined together on the merits.

In view of these inconsistencies, the Office has not established a clear record as required by MPEP 814, which states:

> The examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121. Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381, 68 USPQ2d 1865, 1871 (Fed. Cir. 2003). See also MPEP § 804.01.

The claims as currently pending are now considered for unity of invention anew in this decision.

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

The currently pending claims 51-99 may be sorted as follows:

> Group I, claims 51-73, drawn to a process of making the oxazolidinone derivative of Formula I
> Group II, claims 74-95, drawn to the compound of Formula I and composition comprising Formula I
> Group III, claims 96-99, drawn to a method of using the compound of claim 74 for treating bacterial infection.

Concerning the examiner's attempt to divide Claims 51-52 and Claims 53-73, in the final Office action, the following chart aligns the some of various limitations of Claim 51 and 52 (under examination) with Claim 53 (withdrawn from consideration) to establish that Claims 51, 52 and 53 encompass the same embodiments. For this reason, unity of invention is present amongst Claims 51-73 *a priori*.

Claim 51 (under examination)	Claims 52 (under examination)	Claim 53 (withdrawn from examination)
A method for preparing an oxalidinone derivative of Formula (I)	Depends upon claim 51	A method for preparing an oxalidinone derivative of Formula (I)
Identical variables for R1, R'1, R2, R3, R5, R6, R7 and m		Identical variables for R1, R'1, R2, R3, R5, R6, R7 and m
	Reacting compound of Formula (V) under conditions to prepare the compound of Formula (1).	Reacting compound of Formula (V) under conditions to prepare the compound of Formula (1).

In this application, the examiner maintained lack of unity in the Final Office action amongst product and process of making and process of using the product, even though there was no prior art rejection on elected product claims. This was incorrect. If the claimed product is free of the prior art, the examiner should concurrently examine the first method of making and the first method of using the claimed product along with the first product, per 37 CFR 1.475.

Applicants and the examiner have discussed rejoinder practice. In an effort to clarify any mis-interpretations, MPEP 1893.05(d) is cited here to address rejoinder practice for national stage applications in compliance with 35 USC 371:

> If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04. Any nonelected processes of making and/or using an allowable product should be considered for rejoinder**. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product.

Concerning any request for rejoinder between Group I and III, see MPEP 821.04(a) which states in part:

> Where restriction was required between independent or distinct products, or between independent or distinct processes, and all claims directed to an elected invention are allowable, any restriction requirement between the elected invention and any nonelected invention that depends from or otherwise requires all the limitations of an allowable claim should be withdrawn.

Rejoinder between Group I and II would generally have been contingent upon election of a product claim. See MPEP 821.04(b) which says

> However, if applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder.

In this instance, however, because applicants had been assured that the product and process claims would be examined together in the original restriction requirement, and because there is no prior art of record on the product claims, the first product (claims 74-95), the method of making the first product (claims 51-73) and the method of using the first product (Claims 96-99) will be examined together on the merits.

DECISION

The petition is **GRANTED** for the reasons set forth above.

The final Office action mailed 13 August 2008 is hereby vacated.

Because the final Office action has been vacated, the amendment filed 27 August 2009 will be entered.

A pre-appeal conference will be held shortly to discuss the rejections of record over claims 51 and 52.

The application will be forwarded to the examiner for preparation of an Office action on all pending claims consistent with this decision.

Because the extensive delays in initiating prosecution on the merits in this application, the next Office action will be reviewed by the Supervisory Patent Examiner prior to mailing, see MPEP 707.02 second paragraph.

> "The supervisory patent examiners are expected to personally check on the pendency of every application which is up for the third or subsequent Office action with a view to finally concluding its prosecution."

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512 or by facsimile sent to the general Office facsimile number, 571-273-8300.

Remy Yucel
Director, Technology Center 1600